UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

RICHARD J. PINSONNEAULT, Plaintiff, v. ST. JUDE MEDICAL, INC. and PACESETTER, INC., Defendants.	Case No. 12-CV-1717 (PJS/JSM) ORDER
JOSEPH D. HOULETTE, Plaintiff, v. ST. JUDE MEDICAL, INC. and PACESETTER, INC., Defendants.	Case No. 12-CV-1785 (PJS/JSM)
GARY ROUSE, Plaintiff, v. ST. JUDE MEDICAL, INC. and PACESETTER, INC., Defendants.	Case No. 12-CV-2396 (PJS/JSM)

Yvonne M. Flaherty, LOCKRIDGE GRINDAL NAUEN PLLP, for plaintiff Richard J. Pinsonneault.

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Blake Shepard, Jr. and Brian W. Thomson, STINSON LEONARD STREET LLP; Maja C. Eaton and Rebecca K. Wood, SIDLEY AUSTIN LLP; Daniel L. Ring and Andrew E. Tauber, MAYER BROWN LLP, for defendants.

Plaintiffs Richard Pinsonneault, Joseph Houlette, and Gary Rouse were all implanted with Riata defibrillation leads manufactured by defendants St. Jude Medical, Inc. and Pacesetter, Inc. (collectively "St. Jude"). In December 2011, the Food and Drug Administration ("FDA") issued a recall for certain Riata models, including the models that had been implanted in plaintiffs. Plaintiffs' leads were later explanted.

Plaintiffs bring claims of strict liability/manufacturing defect, negligent manufacturing, negligence per se, and negligence res ipsa loquitur. St. Jude moves for summary judgment on the ground that plaintiffs' claims are preempted under 21 U.S.C. § 360k(a). For the reasons that follow, St. Jude's motion is granted in (large) part and denied in (small) part. Specifically, the Court grants St. Jude's motion with respect to all of plaintiffs' claims, save for their claim that the leads were not properly sterilized.

I. BACKGROUND

A. The Riata Leads

The Riata leads are component parts of an implantable cardioverter defibrillator ("ICD") system used to treat heart arrhythmias. Anderson Decl. ¶¶ 4-5. The leads consist of thin, insulated wires that connect the ICD to one or more electrodes in, on, or near the patient's heart. Anderson Decl. ¶ 6. The leads detect the heart's electrical signals and transmit this information to the ICD. Anderson Decl. ¶ 6. The leads also deliver the electrical impulses necessary to restore or maintain normal heart rhythm. Anderson Decl. ¶ 6.

The Riata leads are Class III medical devices regulated by the FDA pursuant to the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq. Class III devices are defined as devices that are "for a use in supporting or sustaining human life," that are "for a use which is of substantial importance in preventing impairment of human health," or that "present[] a potential unreasonable risk of illness or injury . . . ." 21 U.S.C. § 360c(a)(1)(C). Class III devices are subject to a rigorous safety review by the FDA known as "premarket approval" ("PMA"). *See* 21 U.S.C. § 360e; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-20 (2008) (describing the PMA process).

The Riata family of leads evolved from the Ventritex TVL Lead System, to which the FDA granted PMA on May 10, 1996. Neely Decl. ¶ 6 & Ex. A. Generally speaking, after a medical device has received PMA, the manufacturer must submit a PMA Supplement to the FDA before making any change to the device that might that affect the safety or effectiveness of the device. 21 C.F.R. § 814.39(a). St. Jude submitted numerous PMA Supplements relating to the Ventritex TVL Lead System.

In March 2002, the FDA approved PMA Supplement 14, which sought approval for a modified lead under the trade name Riata Series 1500. Neely Decl. ¶ 7 & Ex. B. Over the years, St. Jude sought approval for further modifications to the Riata leads. By the time that the last of plaintiffs' leads was manufactured, St. Jude had submitted (and received approval for) PMA Supplements 15 through 40. Neely Decl. ¶¶ 9-29; Anderson Decl. ¶ 3. Except when it is necessary to distinguish between them, the Court will refer to the original PMA and PMA Supplements 1 through 40 collectively as "the PMA."

B. Discovery

In an initial pretrial scheduling order dated November 1, 2012, Magistrate Judge Mayeron established March 1, 2013 as the deadline for a first phase of discovery limited to the issue of preemption. ECF No. 20 at 2.[1] To help focus that discovery, Judge Mayeron ordered St. Jude to serve plaintiffs with its motion for summary judgment on the issue of preemption near the beginning of the discovery period; plaintiffs' response to that motion would not be due until after the first phase of discovery had closed. ECF No. 20 at 4. St. Jude accordingly served plaintiffs with its preemption motion and supporting documents on November 15, 2012, shortly after discovery began. Keeling Decl. ¶ 3. As it turned out, however, the parties' discovery disputes necessitated a lengthy extension of the discovery schedule.

Because the Riata family of leads originated with PMA Supplement 14, St. Jude originally took the position that it was required to produce only PMA Supplements 14 through 40 (as well as some associated documents, such as the FDA approval letters). Plaintiffs moved to compel production of additional documents, and on March 15, 2013, Magistrate Judge Mayeron ordered St. Jude to produce (among other things) the original Ventritex TVL Lead System PMA and PMA Supplements 1 through 13. ECF No. 68 at 3 ¶ 2.

Judge Mayeron also ordered that plaintiffs could depose Dave Anderson and Elisabeth Neely, the St. Jude officers who had submitted declarations in support of St. Jude's motion for summary judgment. Specifically, Judge Mayeron allowed plaintiffs to depose Anderson and Neely "on the topics of what documents (in any form) are available to determine for the Riata

[1]Unless otherwise indicated, all citations to the Court's electronic docket are to the docket in the *Pinsonneault* case, No. 12-CV-1717.

leads used by the plaintiffs, the manufacturing requirements imposed on these leads by the Federal Food and Drug Administration and defendants' compliance with those requirements." ECF No. 68 at 3 ¶ 1.

Judge Mayeron denied some of plaintiffs' other document requests as overbroad, however, observing that plaintiffs were seeking everything from "the birth of the Riata Leads to the end" and that "this has the appearance of a fishing expedition that is going well beyond what you have alleged in the complaint." ECF No. 95 at 5-6. But Judge Mayeron's denial was essentially without prejudice. She invited plaintiffs to renew their motion to compel — or alternatively to serve more focused discovery requests— after taking the depositions of Anderson and Neely. ECF No. 68 at 3 ¶ 2. Plaintiffs did not object to Judge Mayeron's March 15, 2013 order.

After deposing Anderson and Neely and obtaining the original PMA and PMA Supplements 1 through 40, plaintiffs filed another motion to compel. ECF No. 74. Plaintiffs sought additional documents and sought to compel Anderson and Neely to answer certain questions that they had been instructed not to answer during their depositions. ECF No. 95 at 6. The parties' discovery disputes grew out of a disagreement about whether documents that St. Jude had not submitted to the FDA were nevertheless relevant to the issue of preemption. St. Jude argued that, for preemption purposes, the only relevant documents were documents that had actually been submitted to the FDA during the PMA process — specifically, the PMA and PMA Supplements. (St. Jude also agreed that the FDA's approval letters were relevant.) Plaintiffs sought much more than that, including a broad array of St. Jude's internal documents relating to the Riata leads.

In an October 3, 2013 order, Judge Mayeron granted plaintiffs' motion in part, ordered St. Jude to produce some additional documents, and overruled St. Jude's objections to some of the deposition questions. ECF No. 95. Once again, Judge Mayeron found that many of plaintiffs' discovery requests were "hopelessly" overbroad and that some were too vague to be enforced. ECF No. 95 at 15-16, 17, 22-23, 28, 29-30. Judge Mayeron generally agreed with St. Jude that "the only specifications and procedures that are relevant in this case are those set forth in the applications for PMA approval." ECF No. 95 at 15-16. Judge Mayeron ordered St. Jude to respond only to those requests for production that addressed the manufacturing defects at issue or particular documents referred to in the PMA. ECF No. 95 at 12-13, 21-22. Judge Mayeron indicated that she considered internal product-specification documents to be relevant so long as they were referenced or incorporated into the PMAs and PMA Supplements. ECF No. 95 at 22-23.

In her October 3 order, Judge Mayeron also informed the parties that Phase I discovery would end on November 1, 2013. ECF No. 95 at 2 ¶ 4. Plaintiffs thus had an entire year to conduct discovery on the issue of preemption. Plaintiffs did not object to Judge Mayeron's October 3 order, nor did plaintiffs seek additional time to take discovery.

II. ANALYSIS

A. Standard of Review

Summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute over a fact is "material" only if its resolution might affect the outcome of the lawsuit under the substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248

(1986). A dispute over a fact is "genuine" only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255.

B. General Preemption Principles

The FDCA includes an express preemption clause that provides, in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

As noted, the Riata leads are Class III medical devices for which St. Jude had to receive premarket approval (or "PMA") from the FDA. An applicant for PMA must submit a broad array of information to the FDA, including "a full statement of the components, ingredients, and properties and of the principle or principles of operation" of the device and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation" of the device. 21 U.S.C. § 360e(c)(1). The FDA may also require the applicant to submit any additional relevant information that the FDA deems necessary. 21 U.S.C. § 360e(c)(1)(H).

As the Supreme Court explained in *Riegel v. Medtronic, Inc.*, a device that has received PMA must "be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." 552 U.S. 312, 323 (2008); *see also* 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). For that reason, the Court held that the PMA process imposes "requirement[s] applicable under this chapter to the device" for purposes of § 360k(a)(1). *Riegel*, 552 U.S. at 322-23.

The Court further held that state common-law duties impose "requirement[s]" that, notwithstanding their general nature, are "with respect to" medical devices for purposes of § 360k(a). *Id.* at 323-25. As a result, if the common law of a state imposes a requirement "different from, or in addition to" the federal requirements imposed through the PMA process, that common-law requirement is expressly preempted by § 360k(a) (assuming that the requirement "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter" — a provision that is not at issue in this case). *Id.* at 330. Therefore, the only kind of state-law claim that is *not* expressly preempted by § 360k(a) is a so-called "parallel" claim — that is, a claim alleging that the defendant has violated a state-law duty that does not differ in any material respect from a federal requirement applicable to the device. *Id.*

C. Plaintiffs' Claims

Plaintiffs' Riata leads were approved through the PMA process, and thus there is no question that federal requirements apply to the leads for purposes of § 360k(a). To escape preemption, then, plaintiffs' claims must be based on state-law requirements that are the same as the applicable federal requirements.

As noted, plaintiffs bring state-law claims of strict liability/manufacturing defect, negligent manufacturing, negligence per se, and negligence res ipsa loquitur. The basis of all of these claims is that the Riata leads were defectively manufactured. Specifically, plaintiffs claim that St. Jude (1) failed to manufacture the leads with uniform insulation thickness;[2] (2) failed to apply a controlled, uniform degree of force when crimping the lead wires; (3) failed to comply with approved methods and specifications for curing; (4) failed to consistently apply a lubricious interface between the inner and outer insulation; and (5) failed to comply with approved methods and specifications for sterilizing.

With respect to the fifth alleged defect — failure to comply with approved methods and specifications for sterilizing the leads — St. Jude admits that the PMA requires the Riata leads to be sterilized in a particular manner, but contends that the leads were in fact sterilized in that manner. Anderson Decl. ¶¶ 15, 18. The Court agrees with plaintiffs, however, that this issue goes to the merits of plaintiffs' claims rather than to the issue of preemption and is therefore

[2]Plaintiffs refer to this requirement as the insulation "diameter." Anderson testified that "diameter" in this context is nonsensical and that the relevant measurement is "thickness." Anderson Dep. 118-19. Plaintiffs respond that "thickness" and "diameter" are equivalent. The Court agrees with plaintiffs to the extent that plaintiffs' allegation is that the insulation tube encasing the wires had to be of a certain uniform thickness.

beyond the scope of this motion. For that reason, St. Jude's summary-judgment motion is denied without prejudice insofar as that motion pertains to plaintiffs' sterilization claims.[3]

With respect to the remaining alleged defects, St. Jude offers evidence that the FDA did not impose the particular requirements that plaintiffs allege were violated. *See* Anderson Decl. ¶ 13 (no federal requirement that insulation diameters be consistent); *id.* ¶ 14 (no federal requirement with respect to curing); *id.* ¶ 16 (no federal requirement that there be a controlled, uniform degree of force used when crimping); *id.* ¶ 17 (no federal requirement that a lubricious interface be applied between the inner and outer insulation). Because the FDA did not impose these particular requirements, St. Jude argues, plaintiffs' state-law claims seek to impose state requirements "different from, or in addition to" the federal requirements applicable to the leads. 21 U.S.C. § 360k(a)(1). For that reason, says St. Jude, plaintiffs' claims with respect to these four alleged defects are preempted.

In response, plaintiffs have filed an affidavit under Fed. R. Civ. P. 56(d) contending that they have not had sufficient time to take discovery to determine whether there are federal requirements concerning insulation thickness, crimp force, curing, or lubricious interface. Plaintiffs also argue that the existing record contains evidence of such federal requirements. The Court considers each argument in turn.

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[3]Needless to say, unless plaintiffs obtain evidence that what St. Jude says is untrue — i.e., evidence that St. Jude did not, in fact, sterilize the leads in the manner required by the PMA — plaintiffs should voluntarily withdraw their sterilization claims and not require St. Jude to bring (and this Court to rule on) another summary-judgment motion. *See* Fed. R. Civ. P. 11(b)(3) (prohibiting a lawyer from "later advocating" a factual contention that does not have "evidentiary support").

1. Rule 56(d) Affidavit

Rule 56(d) is designed to ensure that the party opposing summary judgment has had adequate time for discovery. *See Ray v. Am. Airlines, Inc.*, 609 F.3d 917, 923 (8th Cir. 2010). Under Rule 56(d), a court may permit additional discovery "[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition . . . ." But the rule "is not a shield that can be raised to block a motion for summary judgment without even the slightest showing by the opposing party that his opposition is meritorious." *Willmar Poultry Co. v. Morton-Norwich Prods., Inc.*, 520 F.2d 289, 297 (8th Cir. 1975). To justify additional discovery, a Rule 56(d) affidavit must set forth "(1) what facts are sought and how they are to be obtained; (2) how these facts are reasonably expected to raise a genuine issue of material fact; (3) what efforts the affiant has made to obtain them; and (4) why the affiant's efforts were unsuccessful." *Johnson v. United States*, 534 F.3d 958, 965 (8th Cir. 2008).

As described earlier, plaintiffs had an entire year — from November 1, 2012 to November 1, 2013 — to conduct discovery on just one issue: preemption. During the course of that year, various disputes arose between the parties concerning the proper scope of discovery. In particular, plaintiffs argued that they were entitled not just to the PMA, but to documents referenced in the PMA. To resolve these disputes, plaintiffs brought two motions to compel, which Judge Mayeron granted in part and denied in part. Under the local rules of this District, plaintiffs had two weeks within which to object to Judge Mayeron's rulings. D. Minn. L.R. 72.2(a). Plaintiffs did not file any objection to either of Judge Mayeron's orders. Instead, plaintiffs waited until after the close of discovery — when their summary-judgment response was

due — to complain about the lack of discovery. In essence, then, plaintiffs are using their response to defendants' summary-judgment motion to attempt to bring an untimely and improper challenge to Judge Mayeron's discovery orders. *Id.* ("A party may not assign as error a defect in the order not timely objected to.").

The Court does not credit plaintiffs' conclusory assertion that the need for additional discovery only became clear shortly before discovery closed on November 1, 2013. Plaintiffs had been in possession of St. Jude's motion for summary judgment for nearly a year by the time discovery closed. In addition, all of the discovery arguments that plaintiffs are currently making echo arguments that they made before Judge Mayeron. Indeed, Judge Mayeron *agreed* with many of their arguments; in particular, she permitted plaintiffs to discover documents referenced in the PMA and generally agreed with plaintiffs that such documents are discoverable. *See* ECF No. 95 at 18-23. To the extent that Judge Mayeron denied plaintiffs' requests for such documents, she did so because she found that plaintiffs' requests were overbroad and that plaintiffs had not made any efforts to make them more manageable. *Id.* at 22-23.

The Court sees no error in Judge Mayeron's analysis, and plaintiffs do not explain how it is flawed. Instead, they misleadingly imply that Judge Mayeron categorically denied discovery of documents referenced in the PMA. *See* Hr'g Tr. 5-6, Jan. 6, 2014 [ECF No. 116]. That is simply not true. Plaintiffs' objections to Judge Mayeron's orders are therefore not only untimely, but misleading and meritless. For these reasons alone, the Court denies plaintiffs' Rule 56(d) request for additional discovery. *See Chambers v. The Travelers Cos.*, 764 F. Supp. 2d 1071, 1082-83 (D. Minn. 2011) (denying Rule 56(d) request based in part on plaintiff's failure to object to discovery orders during nearly a year of discovery), *aff'd*, 668 F.3d 559 (8th Cir. 2012); *Beatty v.*

Synthes (USA), 101 Fed. Appx. 645, 646 (8th Cir. 2004) (per curiam) (Rule 56(d) "is designed to minister to the vigilant, not to those who slumber upon perceptible rights" (citation and quotations omitted)).

Even if plaintiffs' Rule 56(d) affidavit was not an improper attempt to circumvent the scheduling order and the local rules governing discovery disputes, the Court would deny plaintiffs' request for more discovery. Plaintiffs' main complaint is that St. Jude should have produced each and every document referenced in the PMA. *See* 21 C.F.R. § 814.3(e) and (g) (defining the PMA and PMA Supplements to include "all information submitted with or incorporated by reference therein"). But despite having ample time during discovery to identify and request such documents, neither plaintiffs' brief nor their Rule 56(d) affidavit identifies any such document that they seek to discover, much less explains why any such document is discoverable. Thus, even if the Court were to agree with plaintiffs that every single document mentioned in a PMA becomes part of that PMA by virtue of § 814.3, plaintiffs' Rule 56(d) affidavit would not entitled them to further discovery.

Plaintiffs had received the original PMA and all 40 relevant PMA Supplements by the middle of March 2013. ECF No. 71 at 2; Keeling Decl. ¶¶ 3-4, 11. This means that many months before discovery closed, plaintiffs had the ability to identify every single document that was incorporated by reference into the PMA.[4] After March 2013, plaintiffs were given the

[4]Plaintiffs contend that no one at St. Jude really knows what was submitted to the FDA, thereby seeming to suggest that there may be other documents that are not referenced in the PMA but are nevertheless part of the PMA because they were submitted to the FDA. But any such suggestion would be pure speculation, and even if such mystery documents exist, plaintiffs had ample opportunity to pursue those documents during discovery. Plaintiffs have not described what steps they could now take to determine whether there were some unknown submissions to

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opportunity to depose two witnesses specifically for the purpose of identifying documents relevant to preemption. Under these circumstances, plaintiffs should now be able to (1) identify the specific documents that they need in order to respond to St. Jude's motion for summary judgment; (2) cite to the Court precisely where those documents are referred to in the PMA (or precisely what evidence suggests that those documents were at least submitted to the FDA) so that the Court can assess plaintiffs' argument that the information in the documents is "incorporated by reference" under § 814.3(e) and (g); and (3) cite evidence supporting their contention that the referenced documents relate in some way to the alleged federal requirements at issue in this case. Yet plaintiffs make no attempt to do any of these things. Nor do plaintiffs identify a single additional witness whom they wish to depose. Without providing such information — which plaintiffs should easily be able to do, given the extensive discovery that has already taken place — plaintiffs have not come close to showing that they are entitled to additional discovery.

It should be noted that plaintiffs have attached their last few discovery requests as exhibits to their Rule 56(d) affidavit. *See* Flaherty Aff. Exs. F, G, J. But plaintiffs do not discuss these requests in any substantive way, nor do they indicate whether or how St. Jude responded. Notably, while one of plaintiffs' earlier requests seeks particular, identified documents (Exhibit G), plaintiffs' final request no longer seeks those documents (Exhibit J), suggesting that St. Jude produced them at some point before the final request was served. It is therefore entirely

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[4](...continued)
the FDA, much less explained why they could not have taken those steps during the year that they were given to take discovery on the preemption issue. *See Johnson*, 534 F.3d at 965 (proper Rule 56(d) affidavit must specify, among other things, how the desired information is to be obtained).

unclear what documents plaintiffs are currently seeking or why plaintiffs believe they are entitled to those documents. At this late stage, plaintiffs' failure to be more specific is inexcusable and strongly suggests that they are simply grasping at straws. *See Gardner v. Howard*, 109 F.3d 427, 431 (8th Cir. 1997) (without a "specific showing" of what evidence could be obtained through further discovery, Rule 56(d) "does not condone a fishing expedition").

To the extent that plaintiffs may be seeking documents that they cannot identify because they were neither referenced in the PMA nor submitted to the FDA, the Court agrees with St. Jude that such documents are not relevant to preemption. Plaintiffs contend that they are entitled to St. Jude's purely internal documents by virtue of 21 C.F.R. § 820.70(a), which requires device manufacturers to develop and document manufacturing processes ensuring that devices conform to their specifications. Section 820.70 is part of the FDA's Quality System Regulation ("QSR"), 21 C.F.R. part 820, which sets forth "Current Good Manufacturing Practices" ("CGMP").

Courts have split over whether alleging a violation of the QSR or the CGMPs is sufficient to state a claim under Fed. R. Civ. P. 12(b)(6). *Compare Bausch v. Stryker Corp.*, 630 F.3d 546, 554-56 (7th Cir. 2010) (holding that alleging a violation of the QSR and CGMPs was sufficient to state a claim) *with In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009) (holding that the QSR and CGMPs are "simply too generic, standing alone, to serve as the basis for Plaintiffs' manufacturing-defect claims"), *aff'd*, 623 F.3d 1200 (8th Cir. 2010). In this case, however, plaintiffs do not contend that St. Jude violated § 820.70(a) or any other part of the QSR. *See* Hr'g Tr. 16-18, 57-58. To the contrary, plaintiffs contend that St. Jude *complied* with § 820.70(a) — and that, as a result, St. Jude must have

established internal manufacturing specifications, and those internal manufacturing specifications must be deemed to be federal requirements for purposes of § 360k(a).

The Court disagrees. Plaintiffs have cited no case, and the Court has found none, holding that purely internal manufacturing specifications constitute federal requirements for purposes of § 360k(a). The absence of such case law is not surprising, as such a holding would plainly be at odds with the fact that the QSR purposely does not prescribe specific manufacturing processes in order to give manufacturers a measure of flexibility. *See* Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52602, 52603 (Oct. 7, 1996).

Moreover, plaintiffs' argument proves too much. If § 820.70(a) transforms a manufacturer's own internal specifications into federal requirements, then *all* devices regulated under that provision — not just Class III medical devices subject to the PMA process — would be subject to detailed and specific federal requirements that would preempt additional or different state requirements. *See* 21 C.F.R. § 820.1(a)(1) ("The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use."); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 152 (S.D.N.Y 2011) ("Medical devices in general, not just Class III devices, are subject to the FDA's current good manufacturing practice requirements (CGMP requirements)."). This result would not only be a terrible blow to the plaintiffs' bar, but it would be at odds with *Medtronic, Inc. v. Lohr*, in which the Supreme Court held that the CGMPs did not preempt state-law claims concerning a Class III device that was exempt from the PMA process. 518 U.S. 470, 497-501 (1996).

Finally, plaintiffs also note that federal requirements may exist outside of the PMA submission, such as in FDA files to which a PMA applicant may refer or in device-specific conditions or restrictions imposed by the FDA. *See* ECF No. 105 at 9-10. That may be so, but plaintiffs cite nothing suggesting that such requirements exist in this case, nor do plaintiffs explain why they would need discovery into such matters as FDA regulations. In short, plaintiffs have fallen far short of demonstrating that they are entitled to yet more discovery under Rule 56(d).

2. Evidence of Requirements

Plaintiffs next argue that there is evidence in the existing record demonstrating that there are federal requirements relating to insulation thickness, crimp force, curing, and lubricious interface.[5] Before examining the evidence, the Court notes that plaintiffs argue that preemption is an affirmative defense for which St. Jude bears the burden of proof. *See Williams v. Nat'l Football League*, 582 F.3d 863, 880 (8th Cir. 2009). Plaintiffs ignore, however, that St. Jude has met its burden; it has come forward with evidence that, standing alone, proves by a preponderance of the evidence that there are no federal requirements with respect to insulation thickness, crimp force, curing, or lubricious interface. If there are no such federal requirements, then plaintiffs' state-law claims would impose requirements "in addition to" the requirements imposed on the device by virtue of the PMA process. 21 U.S.C. § 360k(a)(1); *Riegel*, 552 U.S.

[5]In their brief, plaintiffs also argued that, if there are no such federal requirements, then their state-law claims on those subjects cannot be preempted. Plaintiffs withdrew this contention at oral argument. Hr'g Tr. 54-56. This was wise, as it plainly contradicts § 360k(a) and *Riegel*. Under *Riegel*, there is no doubt that the PMA process imposed federal requirements on the Riata leads, and any attempt to impose additional requirements is therefore clearly preempted under § 360k(a). Plaintiffs' argument to the contrary was simply an attempt to reargue *Riegel*.

at 322-23. In order to prevail, therefore, plaintiffs must cite evidence demonstrating that there are, in fact, federal requirements on these subjects. The Court now examines plaintiffs' evidence.[6]

a. Insulation Thickness

As discussed above, the Riata leads consist of wires that connect an ICD device to electrodes on or near a patient's heart. The wires are encased in a silicone tube of insulation that has four holes or "lumens" bored through it lengthwise to hold the wires. Plaintiffs allege that St. Jude failed to manufacture this tube with uniform thickness, which led to an increased risk that the wires would protrude through areas of thin insulation. Pinsonneault Am. Compl. ¶¶ 48-50; Houlette Am. Compl. ¶¶ 47-49; Rouse Am. Compl. ¶¶ 46-48.

To support their claim that the leads must be manufactured with uniform insulation thickness, plaintiffs point to evidence that the PMA required the overall outer-body diameter of

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[6]Ten days after the close of briefing on St. Jude's motion and just a few days before the hearing, plaintiffs filed additional exhibits and an accompanying affidavit. *See* ECF No. 111. Plaintiffs did not obtain the Court's permission for these belated filings, nor did they offer any explanation to justify their late submission. Because plaintiffs filed these materials in violation of the briefing schedule and the local rules, the materials are not part of the record, and the Court will not consider them. ECF No. 96; D. Minn. L.R. 7.1(c)(2).

The Court notes that, even if it did consider these materials, they would not help plaintiffs avoid summary judgment. Plaintiffs filed these materials well after the close of briefing, and thus plaintiffs neither cited nor explained the materials in their brief, and the Court has no independent obligation to scour the materials for evidence that supports plaintiffs' claims. *See* Fed. R. Civ. P. 56(c)(3); *Rodgers v. City of Des Moines*, 435 F.3d 904, 908 (8th Cir. 2006) ("Without some guidance, we will not mine a summary judgment record searching for nuggets of factual disputes to gild a party's arguments."). This admonition also applies to plaintiffs' habit of repeatedly citing entire depositions and lengthy technical documents without providing pincites. *See, e.g.*, ECF No. 105 at 9-11. The Court should not have to read an entire deposition to try to identify what testimony plaintiffs are relying on. That said, the Court has done its best to examine the record that is properly before it.

the lead to be .088 inches and the maximum body diameter at the location of the shock electrodes to be no greater than .105 inches. Anderson Dep. 215-16. Plaintiffs also point to evidence that the PMA required the insulation tube to be free from nicks and other defects that are greater than 20 percent of the wall thickness. Anderson Dep. 233-34; Flaherty Aff. Ex. N § 8.2.[7] Finally, at oral argument, plaintiffs pointed out that the PMA specifies that the "inner lumen of the lead shall accept a 0.016 inch tapered, ball-tipped stylet. . . ."[8] Hr'g Tr. 39-40; Flaherty Aff. Ex. N § 5.1.2.9. Plaintiffs argue that, given these specifications, there is logically and necessarily a uniform-thickness requirement for the insulation.[9]

The Court does not agree. The thickness of the insulation depends on the overall diameter of the lead body as well as on the placement and size of the lumens inside the insulation. But plaintiffs cite no evidence of any requirement as to the placement of the lumens. Nor, with respect to three of the four lumens, do plaintiffs cite any evidence of any requirement as to their size. To the contrary, the record indicates that there are no such requirements. *See*

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[7]There is some dispute over whether the document from which these specifications are taken — which is labeled PS0069 — was actually part of the PMA. There is testimony that it was submitted to the FDA, however. Anderson Dep. 218 (identifying PS0069 as Neely exhibit 26); *id*. at 231 (testifying that Neely 26 was submitted to the FDA). The Court therefore treats it as part of the PMA for purposes of St. Jude's motion.

[8]Plaintiffs also mentioned an inner-lumen specification in a document entitled QTR 1403. Hr'g Tr. 44. Plaintiffs did not submit QTR 1403 with their brief in opposition to summary judgment, however. (As noted earlier, the Court disregards plaintiffs' late-filed exhibits.) In any event, based on plaintiffs' description, the QTR 1403 specification concerns only one of the four lumens. The Court's analysis therefore remains the same.

[9]Plaintiffs also cite to testimony concerning specifications for insulation thickness. *See* Anderson Dep. 119. There is no evidence that those specifications were submitted to the FDA, however, *see* Anderson Dep. 122-23, 239, and plaintiffs point to no evidence that they are contained in a document incorporated by reference in the PMA.

Anderson Dep. 216 ("We don't specify the lumen in that way. I mean, you could say theoretically the lumen can't be larger than the maximum diameter. That would be a logical argument but that is not one of our specifications."); *Id.* at 218 ("Q. And is there something in this document that tells us how big the lumens are going to be . . . ? A. No.").

Because the spacing and size of the lumens can vary (at least with respect to three of the four lumens), the insulation could be any thickness at any particular point. The only limit is the outer-body diameter requirement for the entire lead, but that simply sets a maximum diameter for the insulation; it does not require that the insulation be uniform or that it be of any particular thickness between the outer edge of the insulation and a lumen encasing a wire. Nor is it true, as plaintiffs argue, that the prohibition on nicks or other defects greater than 20 percent of the wall thickness necessarily means that the insulation must be a particular thickness. A percentage, by its nature, can apply to any number. The prohibition on nicks simply means that, whatever the dimensions of the insulation in any particular lead, any nick or other defect cannot exceed 20 percent of that dimension.

Plaintiffs also contend that St. Jude provided the FDA with a sample lead as part of the PMA application, and that the dimensions of that sample lead — including the dimensions of the insulation — thereafter became federal requirements. But plaintiffs cite no evidence that St. Jude provided a sample lead with its PMA application, much less evidence that any such sample had a uniform insulation thickness. *See* ECF No. 105 at 11. The statute and regulations do not require manufacturers to submit samples; instead, the FDA is authorized to request samples, which the FDA may or may not do in connection with any particular application. *See* 21 U.S.C. § 360e(c)(1)(E) (PMA application shall contain "such samples of such device and of components

thereof *as the Secretary may reasonably require*" (emphasis added)); 21 C.F.R. § 814.20(b)(9) (PMA application shall include "[o]ne or more samples of the device and its components, *if requested by FDA*" (emphasis added)). In sum, there is no evidence in the record that the FDA required that the Riata leads be made with uniform insulation thickness. As a result, plaintiffs' claims that the leads were defectively manufactured because the insulation was not of a uniform thickness are preempted.

b. Crimp Force

Plaintiffs allege that St. Jude failed to apply a "controlled, uniform degree of force" when crimping the lead wires, which resulted in insecure crimps over the length of the leads. Pinsonneault Am. Compl. ¶ 53; Houlette Am. Compl. ¶ 52; Rouse Am. Compl. ¶ 51. To support their claim that the FDA imposed such a requirement, plaintiffs offer a "crimp schedule" which refers to crimp depth "[r]equirement[s]." Flaherty Aff. Ex. Q at 0000007. Plaintiffs cite no evidence that this document is part of the PMA, however.

Setting that aside, the only competent testimony before the Court is that the required crimp depths can be achieved with a range of forces and that there is no requirement for a controlled, uniform degree of force when crimping. Anderson Dep. 287. Plaintiffs contend that "[t]hat doesn't sound right," Hr'g Tr. 52, and that "[o]f course, the force applied to the crimp is directly proportional to the resulting crimp depth," ECF No. 105 at 11. Plaintiffs' claims could only be viable, however, if the crimp had to be a particular depth. But that is not the case; the crimp schedule allows for a range of permissible depths. Flaherty Aff. Ex. Q at 0000007. Because there is no evidence of any requirement for a controlled, uniform degree of force when

crimping, plaintiffs' claims that the leads were defective because of the failure to use a controlled, uniform degree of force are preempted.

c. Curing and Lubricious Interface

Finally, plaintiffs allege that St. Jude failed to follow approved methods and specifications for curing and that St. Jude inconsistently applied a lubricious interface between the inner and outer insulation. Pinsonneault Am. Compl. ¶¶ 51-52; Houlette Am. Compl. ¶¶ 50-51; Rouse Am. Compl. ¶¶ 49-50. But plaintiffs admitted at oral argument that they have no evidence of any federal requirements as to curing or lubricious interface. Hr'g Tr. 49 (admitting that plaintiffs have no evidence of a requirement regarding the curing process); Hr'g Tr. 58-59 (admitting that plaintiffs have no evidence of a requirement regarding lubricious interface). Moreover, the only evidence in the record is that the leads do not *have* a lubricious interface between the inner and outer insulation. Anderson Dep. 176-77. Consequently, plaintiffs' claims that the leads were defective because St. Jude failed to follow specifications regarding curing and the application of a lubricious interface are preempted.

For these reasons, the Court grants summary judgment to St. Jude on all of plaintiffs' claims, except for plaintiffs' claims that their leads were not sterilized in the manner required by the PMA.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. Defendants' motions for summary judgment [ECF No. 97 in 12-CV-1717; ECF No. 96 in 12-CV-1785; and ECF No. 92 in 12-CV-2396] are GRANTED IN PART and DENIED IN PART.

2. The motions are DENIED to the extent that they seek dismissal of plaintiffs' claims alleging that defendants failed to comply with state-law requirements that paralleled federal requirements regarding sterilization.

3. The motions are GRANTED in all other respects.

Dated: June 24, 2014

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge